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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/331,204	08/20/1999	ROBERT TAM	216/013-US1	1379

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EXAMINER
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SCHULTZ, JAMES

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 02/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/331,204

Applicant(s)

TAM, ROBERT

Examiner

J. Douglas Schultz

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 19 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 11, 12, 14-17 and 19-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11, 12, 14-17 and 19-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

1. The indicated allowability of claims 11, 12, 14-17, and 19-25 is withdrawn in view of the newly discovered reference(s) to Tam et al., (U. S. Patent Number 5,932,556, "Tam I") and Tam et al. (WO 96/24380, "Tam II"). Rejections based on the newly cited reference(s) follow.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. Applicant's response filed December 19, 2003 has been considered. Rejections and/or objections not reiterated from the previous office action mailed October 31, 2003 are hereby withdrawn. The following rejections and/or objections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application.

### *Response to Rejections - 35 USC § 112*

4. Claims 11, 12, 14-17, and 19-25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a **new matter** rejection, and is repeated for the same reasons of record as set forth in the Office action mailed October 31, 2003.

Applicants' response does not address this rejection, which is therefore maintained.

***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 11, 12, 14, 15, 17, and 19-25 are rejected under 35 U.S.C. 102(a) as being anticipated by Tam II et al.

The claims of the instant invention are drawn to aptamers having a length between 13 and 22 nucleic acid units includes at least two G-rich regions selected from the group consisting of GGnG, GGGG, GnGG, nGGG and GGGn, where G is deoxyguanosine and n is any nucleotide, and wherein the nucleic acid units in the aptamer and the at least two G-rich regions are selected such that the aptamer reduces CD28 expression in an activated human T-cell and wherein the aptamer is selected from the group consisting of SEQ ID NOS: 4, 5, 7 or 8, and methods of use thereof.

The instant application was filed under 35 U.S.C. § 371, which claims priority to PCT/US97/23927, which claims priority to U. S. Provisional Application Number 60/034,509, filed December 27, 1996. A review of the provisional application indicates that said provisional application provides adequate support for the instant sequences, and thus the claims above are accorded the earliest priority date of December 27, 1996.

Tam II discloses oligonucleotides that are between 13 and 22 nucleic acid units, that include at least two G-rich regions selected from the group consisting of GGnG, GGGG, GnGG, nGGG and GGGn, where G is deoxyguanosine and n is any nucleotide, and wherein the

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aptamers reduces CD28 expression in an activated human T-cell, and wherein the aptamer is selected from the group consisting of SEQ ID NOS: 4, 5, 7 or 8. These correspond to SEQ ID NOS: 3, 50, 51 and 52 of Tam II, respectively. Tam II also discloses methods of using said aptamer.

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 16 is rejected under 35 U.S.C. 102(b) as being anticipated by Tam II.

The claim is directed to the subject matter described above, wherein the oligonucleotide comprises SEQ ID NO: 6.

The instant application was filed under 35 U.S.C. § 371, which claims priority to PCT/US97/23927, which claims priority to U. S. Provisional Application Number 60/034,509, filed December 27, 1996. A review of the provisional application indicates that said provisional application **does not** provides support for SEQ ID NO: 6 since no reference to said SEQ ID NO:6 can be found in said document, and thus the claim is accorded the priority date of the instant application, December 19, 1997.

Tam II discloses an oligonucleotide between 13 and 22 nucleic acid units, that includes at least two G-rich regions selected from the group consisting of GGnG, GGGG, GnGG, nGGG and GGGn, where G is deoxyguanosine and n is any nucleotide, and wherein the aptamer reduces CD28 expression in an activated human T-cell, and wherein the aptamer comprises SEQ

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ID NO: 6. This corresponds to SEQ ID NO:4 of Tam II, respectively. Tam II also discloses methods of using said aptamer.

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 11, 12, 14-17, and 19-25 are rejected under 35 U.S.C. 102(e) as being anticipated by Tam I.

The claims of the instant invention are drawn to aptamers having a length between 13 and 22 nucleic acid units includes at least two G-rich regions selected from the group consisting of GGnG, GGGG, GnGG, nGGG and GGGn, where G is deoxyguanosine and n is any nucleotide, and wherein the nucleic acid units in the aptamer and the at least two G-rich regions are selected

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such that the aptamer reduces CD28 expression in an activated human T-cell and wherein the aptamer is selected from the group consisting of SEQ ID NOS: 4-8, and methods of use thereof.

Tam I discloses oligonucleotides that are between 13 and 22 nucleic acid units, that include at least two G-rich regions selected from the group consisting of GGnG, GGGG, GnGG, nGGG and GGGn, where G is deoxyguanosine and n is any nucleotide, and wherein the aptamers reduces CD28 expression in an activated human T-cell, and wherein the aptamer is selected from the group consisting of SEQ ID NOS: 4-8. These correspond to SEQ ID NOS: 3, 50, 4, 51 and 52 of Tam I, respectively. Tam I also discloses methods of using said aptamer.

### ***Double Patenting***

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 11, 16, and 17, and 19-25 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 5, and 6 of U.S. Patent No. 5,932,556. Although the conflicting claims are not identical, they are not patentably distinct

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from each other because claims 2, 5 and 6 of the '556 patent claim the same sequences as claimed in the instantly in claims 11 and 16. Furthermore, the method of claim 1 of the '556 patent is drawn to a method of using the claimed aptamers to inhibit CD28 expression, which is not patentably distinct from the method of using the claimed aptamers to inhibit CD28 expression of the instant claims 17-25.

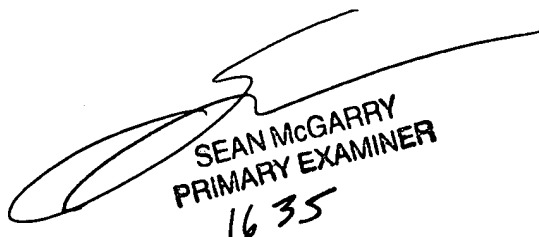
### *Conclusion*

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. Douglas Schultz whose telephone number is 571-272-0763. The examiner can normally be reached on 8:00-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on 703-308-0447. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

James Douglas Schultz, PhD

  
SEAN MCGARRY  
PRIMARY EXAMINER  
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